

Brief Description of the Drawings

Fig. 1 photographically illustrates the visual cue of the device of the present invention. The burr hole cover plate on the left is opaque at room temperature, while the plate on the right has been heated to 55°C is nearly transparent.

Detailed Description of the Invention

The biocompatible polymeric materials described herein are matrices having a continuous phase and a disperse phase. The continuous phase is generally composed of an amorphous biocompatible polymeric material. The dispersed phase is composed of a biocompatible material with a low melting point. The dispersed phase is believed to provide scattering centers in the matrix that when heated become transparent. This provides the surgeon a visual cue of when to bend and shape the medical device formed from the matrix. In applications that require shaping the device, such as cranial plating over a variety of bony contours, the present invention is far superior to the devices disclosed in the prior art.

The polymeric materials of the present invention are formed of a polymeric matrix with a continuous phase and a dispersed phase of a lower melting crystalline material forming a second distinct phase. The continuous phase is preferably formed from amorphous

biocompatible polymers. Suitable amorphous
biocompatible polymers include, but are not limited to,
amorphous aliphatic ester polymers selected from the
group consisting of amorphous polylactide (including D-
5 lactide, L-lactide, mixtures of D-lactide and L-lactide,
as well as, lactic acid polymers), amorphous
polyglycolide (including polyglycolic acid polymers),
amorphous poly-1,4-dioxan-2-one, amorphous
polytrimethylene carbonate (also known as poly-1,3-
10 dioxan-2-one) and copolymers and blends thereof. For
crystalline compositions the polymers will have a
melting point above 80°C and most preferably above 70°C.

The dispersed phase is a semi-crystalline polymer that
15 will form a separate phase in the continuous matrix and
melt at a temperature between about 40°C to about 65°C,
and most preferably will melt at a temperature in the
range of from about 40°C to about 55°C. Suitable
absorbable biocompatible polymers that may used
20 especially in association with the aliphatic ester
polymers listed for the dispersed phase include, but are
not limited to, biocompatible absorbable polymers
selected from the group consisting of poly(ϵ -
caprolactone); copolymers of ϵ -caprolactone and with up
25 to 40 mole percent of a second monomer selected from the
group consisting of lactide (lactic acid), glycolide
(glycolic acid), 1,4-dioxan-2-one, and trimethylene
carbonate; and copolymers of ϵ -caprolactone or
trimethylene carbonate with greater than 60 mole percent
30 1,4-dioxan-2-one, but less than 90 mole percent.

Additionally, the dispersed phase may be formed from low melting biocompatible organic molecules of an appropriate size to act as scattering sites that may be blended with the matrix without adversely affecting the chemical or mechanical properties of the matrix polymer for its intended use. One suitable organic material is polyethylene glycol (PEG).

Additionally, the continuous phase and the dispersed phase could also be provided by using block copolymers composed of the continuous phase and dispersed phase polymers described above, provided that the block copolymers formed two distinct phases, wherein the dispersed phase block forms scattering sites and the dispersed phase has a melting point in the temperature range previously described.

Generally, the amount of biocompatible material in the dispersed phase will be that amount sufficient to provide a visual cue when the biocompatible materials in the dispersed phase become transparent or melt or otherwise visually changes during heating of the device. By way of a guideline, but not limiting the scope of the present invention, for the combination of the continuous phase aliphatic polyesters previously listed with the dispersed phase biocompatible absorbable polymers previously listed, it is preferred that the weight percent of dispersed polymer comprise in the range of from about 1 to about 50 and most preferable from about 2 to about 20. The weight percentages being based on